September 25, 2000

Office of Device Evaluation
Document Mail Center (HFZ- 401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Ladies and Gentlemen:

Re: Reclassification Petition for Metal/Metal Semi-Constrained Hip Joint Prostheses with Cemented and Uncemented Acetabular Components; 21 CFR 888.320 and 888.330

Enclosed in triplicate is a petition for the referenced devices requesting reclassification by FDA from Class III to Class II. This petition is being submitted by the Orthopaedic Surgical Manufacturers Association (OSMA) under Section 5 13 (e) (1) [Title 21 United States Code 360c].

Under separate cover and at FDA's request, four (4) additional "desk copies" of this reclassification petition are also being submitted. The desk copies are identical to the enclosed documents and should not be considered as a separate submission.

Please contact the undersigned at (901) 399-6142 if there are any questions or if further information is required.

Sincerely,

Tom Craig

Enclosures

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